

Notice of Allowability

Application No.

10/009,698

Applicant(s)

POPE ET AL.

Examiner

Art Unit

Khatol S Shahnan-Shah

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to applicants' communications of June 1, 2004.
2. ☒ The allowed claim(s) is/are 1-8, 11-17 and 20-27, renumbered claims 1-23 respectively.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Attachment to Notice of Allowance

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/01/04 has been entered.
2. Applicants' response and declaration under 37 C.F.R. 1.132, received 01 June 2004 are acknowledged. The declaration is proper. It has been considered and entered. The declaration of Dr. Victoria Pope under 37 CFR 1.132 filed 6/1/04 is sufficient to overcome the rejection of claims 1-8, 11-17 and 20-27 under 35 U.S.C. 103 (a), based upon evidence of unexpected superior results.
3. Claims 1-8, 11-17 and 20-27 are pending and under consideration.

Rejections Withdrawn

4. Rejection of claims 1-8, 11-17 and 20-27 under 35 U.S.C. 103, (a) made in paragraphs 15, 16, 19 and 20 of the office action mailed 11/23/2003 is withdrawn in view of applicants' response and declaration.

Allowable Subject Matter

5. Claims 1-8, 11-17 and 20-27 are allowed. Claims are renumbered 1-23 respectively.

The following is an examiner's statement of reasons for allowance:

Claims are drawn to a composition and a method of detecting anti-lipoidal antibodies in a human comprising combining a biological sample from the human with a composition comprising tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine and

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detecting an immunocomplex formed between an anti-lipoidal antibody in the biological sample and the composition.

The prior art fails to teach the particular claimed composition. While, individual lipids tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine are known in the art. However, the particular composition combining these two synthetic compounds has not been taught nor suggested in the prior art. The prior art does teach a motivation to combine them either. Other than applicants' own work (i.e specification, declaration and exhibits from the inventor's laboratory notes) there has not been any suggestion in the art to combine these two particular synthetic cardiolipin and lecithin. The applicants have shown that the combination of synthetic tetramyristoyl cardiolipin and 1-palmitoyl-2-oleoyl-*sn*-glycero-3-phosphocholine provides an unexpectedly superior antigen composition when compared to the VDRL antigen described in the prior art. Likewise the method of using the particular synthetic composition has not been taught nor suggested in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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June 22, 2004



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

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